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The Department of Vermont Health Access Medical Policy

Subject: Proton Beam Therapy
Last Review: April 25, 2016
Revision 3:
Revision 2:
Revision 1:
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Description of Service or Procedure

Proton beam therapy is a type of radiation therapy that uses high energy beams to treat tumors. In proton beam therapy, energy comes from protons, the positively charged parts of an atom. Protons are generated by a powerful machine called a particle accelerator. Unlike an X-ray, the proton stops after striking the target. A proton beam can be finely controlled, in both its width and its depth. The power of protons is that higher doses of radiation can be used to control and manage cancer while significantly reducing damage to healthy tissue and vital organs. Irregularly shaped lesions located near critical structures, tumors in children, and large tumors near any critical organ are well suited for proton beam therapy.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule that pertains to the beneficiary's aid category. Prior Authorization (PA) is only valid if the beneficiary is eligible for the applicable item or service on the date of service.

Medicaid Rule

7102.2 Prior Authorization Determination

7103 Medical Necessity

Medicaid Rules can be found at http://humanservices.vermont.gov/on-line-rules

Coverage Position

Proton beam therapy may be covered for beneficiaries:

- When the proton beam therapy is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice in accordance with Vermont

State Practice Act, who is knowledgeable in the use of proton beam therapy and who provides medical care to the beneficiary AND
- When the clinical guidelines below are met.

Coverage Guidelines

Proton beam therapy may be covered for beneficiaries who meet the following and the referral is from the consultant oncologist who has seen and assessed the beneficiary:
- Target volume is close to a critical structure, requiring a steep dose gradient outside the target to limit the structure's exposure. AND
- A decrease in dose inhomogeneity in a large treatment volume is required to avoid an excessive "hotspot" within the target volume. AND
- Use of photon-based therapy carries an increased risk of clinically meaningful normal-tissue toxicity. AND
- The same area or an adjacent area has been previously irradiated, increasing the need for sculpting to limit the cumulative radiation dose. AND
- Utilizes FDA approved Devices.

Clinical guidelines for repeat service or procedure

The same criteria apply as for the initial use.

Type of service or procedure covered

Proton beam therapy is considered reasonable in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the patient. Examples of such an advantage might be:

Group 1
- Ocular tumors, including intraocular melanomas
- Tumors that approach or are located at the base of skull, including but not limited to:
  - Chordoma
  - Chondrosarcomas
- Primary hepatocellular cancer treated in a hypofractionated regimen
- Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated
- Primary or benign solid tumors in children treated with curative intent and occasional palliative treatment of childhood tumors when at least one of the four criteria noted above apply
- Patients with genetic syndromes making total volume of radiation minimization crucial such as but not limited to NF-1 patients and retinoblastoma patients
- Pituitary neoplasm
- Advanced staged (e.g., T4) and/or unresectable malignant lesions of the head and neck
- Malignant lesions of the paranasal sinus, and other accessory sinuses
- Unresectable retroperitoneal sarcoma

Group 2

Coverage is limited to providers who have demonstrated experience in data collection and analysis with a history of publication in the peer-reviewed medical literature.

- Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers
- Advanced stage, unresectable pelvic tumors including those with peri-aortic nodes or malignant lesions of the cervix
- Breast cancers
- Unresectable pancreatic and adrenal tumors
- Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
- Unresectable malignant lesions of the liver, biliary tract, anal canal and rectum
- Prostate cancer, without distant metastases*
- Hodgkin or Non-Hodgkin Lymphoma involving the mediastinum or in non-mediastinal sites where PBT has the potential to reduce the risk of pneumonitis or late effects of radiation therapy (secondary malignancy, cardiovascular disease, or other chronic health conditions)
- Re-irradiation where prior radiation therapy to the site is the governing factor necessitating PBT in lieu of other radiotherapy.

Please note:

- The prostate cancer should be locally contained and not be an advanced prostate cancer (i.e. T3 or T4 where the tumor has spread through the capsule or has invaded seminal vesicles or other structures) and not any N disease (i.e. no spread to lymph nodes or there has been spread to the pelvic lymph nodes). Note: spread into pelvic lymph nodes is considered metastatic disease.

Limitations

- Proton beam therapy is generally not indicated for cancers that are widely disseminated or have hematogenous metastases.
- For the treatment of primary lesions, the intent of treatment should be curative.
- For the treatment of recurrent or metastatic lesions, there should be the expectation at the time of treatment of a long-term benefit (greater than 12 months of life expectancy).
- Primary hepatocellular cancer treated in a hypofractionated regimen
- Malignant lesions of the paranasal sinus, and other accessory sinuses

Type of service or procedure not covered (this list may not be all inclusive)

- Adenoid cystic carcinoma
- Age-related macular degeneration
- Bladder cancer
- Brain and spinal cord tumors
- Carotid body tumor
- Cavernous hemangioma
- Cholangiocarcinoma
- Dermatofibrosarcoma protuberans
- Desmoid fibrosarcoma
- Esophageal cancer
- Ewing's sarcoma

- Fibrosarcoma of the extremities
- Gastrointestinal cancers, including esophageal and pancreatic
- Glioma
- Intracranial arterio-venous malformations
- Kidney cancer
- Laryngeal
- Leiomyosarcoma of the extremities
- Nasopharyngeal tumor
- Non-uveal melanoma
- Parotid gland tumor
- Pituitary neoplasms
- Seminoma
- Small bowel adenocarcinoma
- Soft tissue sarcoma
- Squamous cell carcinoma of the tongue/glottis
- Submandibular gland tumor
- Thymoma
- Tonsillar cancer
- Vestibular tumors (e.g. acoustic neuroma or vestibular schwannoma

References

Agency for Healthcare Research and Quality. (2013). *Guideline summary: proton beam therapy* (Clinical Practice Guideline; No. RT-002). Retrieved February 19, 2016, from: http://guideline.gov/content.aspx?id=45375&search=proton+beam+radiotherapy

Andrews, M. (2014). Insurers hesitant to cover many proton beam therapy treatments. *Kaiser Health News.* Retrieved February 19, 2016, from: http://kaiserhealthnews.org/news/insurers-hesitant-to-cover-many-proton-beam-therapy-treatments/

Finger, P.T. (2013). Choroidal hemangioma. *Eye Cancer Network.* Retrieved February19, 2016, from: http://www.eyecancer.com/patient/condition.aspx?nid=61&category=choroidal+tumors&condition=choroidal+hemangioma

Hayes, Inc. Search and Summary. *Proton Beam Therapy for Prostate Cancer.* Landsdale, PA: Hayes, Inc.; May 2015.

Hayes, Inc. Search and Summary. *Proton Beam Therapy for Medulloblastoma in Children.* Landsdale, PA: Hayes, Inc.; May 2014.

Henderson, R., Hoppe, B., Marcus, Jr. R., Mendenhall, W., Nichols, C., Li, Z. et al. 2013). Urinary function outcomes and toxicity five years after proton therapy for low-and intermediate –risk prostate cancer. *Acta Oncologica Jubilee Article, 52.* RetrievedFebuary 19, 2016, from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3603169/

Medicare Local Coverage Determinations for National Government Services (DL35075). NHIC Corp. Proposed Draft. Retrieved February 17, 2016, from: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36609&ContrId=302&ver=9&ContrVer=1&CntrctrSelected=302*1&Cntrctr=302&DocType=AllProposed&LCntrctr=302*1&bc=AgAAAAIAAAAAAA%3d%3d&

Nguyen, P., Aizer, A., Davis, B., Assimos, D., D'Amico, A., Frank, S. et al. (2013). *American College of Radiology ACR Appropriateness Criteria.* RetrievedFebruary 19, 2016, from: https://acsearch.acr.org/docs/69350/Narrative/

Parthan, A., Pruttivarasin, N., Davies, D., Talor, D., Pawar, V., Bijlani, A. et al. (2012). Comparative cost-effectiveness of sterotactic body radiation verses intensity-modulated and proton radiation therapy for localized prostate cancer. *Frontiers in Oncology, 2.* RetrievedFebruary 19, 2016, from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3422724/

Proton beam radiation therapy. Clinical Practice Guideline, RT-002, version 1. (2013). *Alberta Health Services.* Retrieved February 19, 2016, from: http://www.albertahealthservices.ca/assets/info/hp/cancer/if-hp-cancer-guide-rt002-proton-beam-RT.pdf

Proton beam therapy: ACR appropriateness criteria. Final Evidence Report, 12. (2013). *American College of Radiology (ACR)* Retrieved February 19, 2016, from: http://www.acr.org/Quality-Safety/Appropriateness-Criteria

Proton beam therapy. Astro Model Policies. (2014). *American Medical Association*. Retrieved February 19, 2016, from: http://www.astro.org/uploadedFiles/Main_Site/Practice_Management/Reimbursement/ASTRO%20PBT%20Model%20Policy%20FINAL.pdf

Proton beam therapy. (2014). *Institute for Clinical and Economic Review.* Retrieved February 18, 2016, from: www.icer-review.org/wp-content/uploads/2014/07/pbt_final_report_040114.pdf

Proton therapy. (2015). *National Association for Proton Therapy).* How it works. Retrieved February 18, 2016, from: http://www.proton-therapy.org/howit.htm

Schiller, K.C., Habl, G., & Combs, S.E. (2016). Protons, photons, and the prostate – Is there emerging evidence in the ongoing discussion on particle therapy for the treatment of prostate cancer. *Frontiers in Oncology, 6*(8). Retrieved on February 19, 2016 from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4729886/pdf/fonc-06-00008.pdf

Taylor, N. (2008). FDA beams approval of cancer therapy. *Breaking News on Global Pharmaceutical Technology & Manufacturing.* Retrieved February 19, 2016, from: http://www.in-pharmatechnologist.com/Ingredients/FDA-beams-approval-of-cancer-therapy

The Alliance Dedicated Cancer Centers, National Association of Proton Therapy & Particle Therapy Cooperative Group – North America (2016). Model policy. Coverage of proton beam therapy. Retrieved February 19, 2016 from:http://www.proton-therapy.org/documents/2016_model_policy.pdf

Wisenbaugh, E., Andrews, P., Ferrigni, R., Schild, S., Keole, S., Wong, W. et al. (2014). Proton beam therapy for localized prostate cancer 101: Basics, controversies, and facts. Reviews in Oncology, 16(2). Retrieved February 19, 2015, from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4080851/pdf/RIU016002_0067.pdf

Yu, J.B., Soulos, P.R., Herrin, J., Cramer, L.D., Potosky, A.L., Roberts, K.B. et al. (2013). Proton verses intensity-modulated radiotherapy for prostate cancer: patterns of care and early toxicity. *Journal of the National Cancer Institute, 105(1)*. Retrieved February 19, 2016, from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3536640/

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